

# Whose standard is it, anyway? How the tobacco industry determines the International Organization for Standardization (ISO) standards for tobacco and tobacco products

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## Abstract

**Objective**—To describe the extent of the tobacco industry involvement in establishing international standards for tobacco and tobacco products and the industry influence on the International Organization for Standardization (ISO).

**Methods**—Analysis of tobacco industry documents made public as part of the settlement of the Minnesota Tobacco Trial and the Master Settlement Agreement. Search words included "ISO", "CORESTA", "Barclay", "compensation and machine smoking", "tar and nicotine deliveries", and the name of key players, in different combinations.

**Results**—It is clear that the tobacco industry, through the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA), play a major role in determining the scientific evidence and suggesting the standards that are eventually adopted as international standards for tobacco and tobacco products in several areas, including the measurement of cigarette tar and nicotine yield.

**Conclusions**—ISO's tobacco and tobacco products standards are not adequate to guide tobacco products regulatory policies, and no health claims can be made based on ISO's tobacco products standards. There is an urgent need for tobacco control advocates and groups worldwide to be more involved with the work of the ISO, both directly and through their national standardisation organisations.

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Standards play a key role in the regulation of consumer products. Regulatory agencies throughout the world use standards to evaluate whether or not a product is in compliance with the desirable consumer safety features, and manufacturers worldwide display the seal of approval of the country's national standardisation office or the International Organization for Standardization (ISO) as a symbol of quality.

The ISO, established in 1947, is a "worldwide non-governmental organisation of national standards bodies from some 130 countries" with a mission to "promote the

development of standardisation and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity."<sup>1</sup> ISO standards are used in the development of policies, regulation, and legislation of health and safety matters on a variety of issues.

ISO is made up of its members, which are divided into three categories:

- (1) a member body of ISO is the national body "most representative of standardisation in its country", and there is only one member body per country. Member bodies have the right to be represented on a committee;
- (2) a correspondent member is an "organisation in a country which does not yet have a fully developed national standards activity". Correspondent members "are entitled to be kept fully informed about the work of interest to them";
- (3) subscriber membership, "for countries with very small economies."<sup>1</sup>

Some 2850 technical committees, subcommittees, and working groups carry out the technical work of ISO. Representatives of industry, research institutes, government authorities, non-government organisations, consumer bodies, and international organisations from all over the world participate, directly, in liaison with ISO, or indirectly, through a national member body, in the work of these committees and the development of international standards. (ISO's member bodies are national standards institutions, which in turn have varying degrees of affiliation with their governments, depending on the country.)<sup>1</sup>

The need to develop a standard is usually initiated by an industry sector. Standards result from "consensus agreements reached between all economic players in that industrial sector—suppliers, users, and often government." One of the aims of standards is "to facilitate trade, exchange and technology transfer through... improved health, safety and environmental protection, and reduction of waste."<sup>1</sup> It is important to question if these aims are being met in the case of tobacco and tobacco products standards.

It has been known for decades that the standard ISO measurement to determine tar and nicotine yield (and the slightly different

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US Federal Trade Commission (FTC) method) does not reflect the amount of tar and nicotine delivered to the smoker, a fact that is acknowledged in several published studies, including studies funded by the tobacco industry.<sup>2-6</sup> Both the ISO and the FTC methods, as well as Germany's DIN method, are derived from CORESTA Standard Methods 10 and 12—tar and nicotine determination in cigarette smoke.<sup>7</sup> The methods use a smoking machine to measure the deliveries of these components and were developed to provide a ranking of tar and nicotine yields, and not to determine the health consequences or the amount actually delivered to a smoker. The method specifies the volume and duration of puff over a certain amount of time.<sup>8-10</sup> There are a few differences between these methods that leads to variation in the yield of tar and nicotine measured for the same cigarette brand. Among other differences, the ISO method uses different conditions for smoking, such as temperature, different drafts on the smoking machine, and different cigarette butt length.<sup>11-14</sup>

In addition, cigarette design has been used to "cheat" the smoking machine, providing lower tar and nicotine readings by machine versus human smoking, a fact that has also been widely discussed in the scientific literature. The accompanying misleading labels that claim a cigarette brand is "mild" or "light" and how smokers "compensate" lower yields by changing the manner they smoke, has also been amply discussed, including by the tobacco industry itself.<sup>4-6 8 9 15 16</sup> The FTC, in its proposal to review the cigarette testing methodology, states that the "compensatory smoking behaviour substantially reduces the informative value of the current [tar and nicotine] ratings" and that more accurate information should be provided to consumers.<sup>3</sup>

Like the FTC method, the ISO method can be useful for some ranking in terms of tar and nicotine yield as measured by machine smoking procedures, but it can not be used for consumer information or claims in terms of tar and nicotine actually delivered to the smoker. No health claims can be made based on the ISO/FTC tar and nicotine cigarette yield measurements. Indeed, when the FTC method was adopted, in 1967, it was not to determine "the amount of 'tar' and nicotine inhaled by any human smoker, but rather to determine the amount of tar and nicotine generated when a cigarette is smoked by a machine in accordance with the prescribed method."<sup>8</sup> Nonetheless, ISO standards continue to be used in regulatory and policy settings, and public health concerns continue to be inappropriately mentioned as reasons to lower tar and nicotine yield in cigarette smoke as measured by machine smoking methods. In June 2000 the European Union (EU) started the approval process of a directive that determines new, lower limits of tar, nicotine, and carbon monoxide deliveries based on ISO measurements,<sup>17</sup> despite commentaries from health groups pointing to the inadequacy of the ISO method.<sup>18 19</sup> Although the EU recognised that

all cigarettes are harmful, including those with lower tar and nicotine yield, it stated that tar, nicotine, and carbon monoxide ceilings, as measured by ISO methods (for lack of another international standard and until a better standard is developed), were necessary to "ensure high levels of public health protection."<sup>17</sup> (As of March 2001 the directive has not yet been through all the steps of the approval process, but it is moving rapidly in that direction.)

Considering the massive amount of evidence showing that ISO standards on tobacco and tobacco products are inadequate for health protection purposes, and indeed they were not meant to serve as a health and safety standard, one is puzzled by the fact that there has been no concerted worldwide effort by government and non-government agencies to develop and propose more appropriate performance standards—that is, standards that will permit a better assessment of the cigarette smoke components delivered to the smoker. Among options to address the issue are: on the one hand, as a precautionary measure, the refusal to consider standards that make no provision for health concerns (such as the current ISO standard) when developing regulatory, health related policies and legislation, thus no longer perpetuating the "low tar, low nicotine" myth; and on the other hand, there is the option of increased participation in the work of ISO. So far, health groups and health agencies have largely underestimated the importance of conveying their views and concerns to ISO's committees and thus have failed to counter the influence of the tobacco industry on ISO. However, change might be forthcoming with an increase worldwide interest in the regulation of tobacco products. The final report<sup>20</sup> from the World Health Organization (WHO) sponsored meeting "Advancing knowledge on regulating tobacco products", held in Oslo, Norway in February 2000 to discuss international regulatory issues, acknowledges the inadequacy of using ISO/FTC measurements to determine the health impact of cigarettes, and recommends that measures of tar and nicotine derived from ISO/FTC methods be removed from cigarette packages because of their misleading influence in a health perspective.<sup>20 21</sup>

The issue of standard measurement of tobacco products components is likely to gain even more international visibility as the negotiations for the Framework Convention for Tobacco Control advance and include the regulation of tobacco products among its protocols. As these initiatives move forward, it is important for public health professionals to understand the purposes of such standards and to use them accordingly.<sup>22 23</sup>

This paper describes the extent of the tobacco industry involvement in establishing international standards for tobacco and tobacco products.

## Methods

We analysed the contents of tobacco industry documents made public as part of the settlement of the Minnesota Tobacco Trial and

the Master Settlement Agreement. We searched both tobacco industry and non-tobacco industry websites that placed these documents on the internet. Search words included "ISO", "CORESTA", "Barclay", "compensation and machine smoking", "tar and nicotine deliveries", and the name of key players, in different combinations.

### Results

Industry participation in the development of ISO standards is not exclusive to tobacco, but unlike other products, such as screws and credit cards, the determination of standards by the industry, without the participation of other interested parties, has led to the development of standards that protect the political and commercial interests of the industry rather than those of the consumer. In the case of ISO technical committee 126—tobacco and tobacco products standards (ISO TC/126, established in 1968), the standards are developed in fact by the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA).

#### CORESTA

CORESTA began in 1955 as a research organisation of industry tobacco chemists from around the world. Its membership is dominated by the tobacco industry, including both state monopolies and multinational companies.<sup>24-27</sup>

CORESTA's scientific activities aim to advance the interests of the tobacco industry worldwide,<sup>28</sup> and to pre-empt regulations through the development of its own research and standards.<sup>29-30</sup> For example, a letter from Philip Morris (PM) vice president of international operations services, Manuel Bourlas, to CORESTA's secretary general François Jacob in 1992<sup>31</sup> stated:

"I believe in and continue to support the concept of a collaborative effort in addressing scientific problems related to tobacco as the concept tends to strengthen the industry's position in the scientific world . . .

"I am certain that we could develop a global scientific program which would go beyond the development of measurement techniques while at the same time remain sensitive to proprietary and competitive issues."<sup>31</sup>

CORESTA is one of the many international bodies that work in liaison with ISO.<sup>32</sup> The standards developed under the aegis of ISO/TC 126 are based on the tests and scientific evidence provided by CORESTA. Most individuals involved in the work of ISO/TC 126 are tobacco industry representatives.<sup>33-34</sup> At the 1995 ISO/TC 126 plenary meeting in South Africa, of the 52 individuals present, only seven people identified themselves as representing their national standards body, plus the two people of TC 126 secretariat—the German DIN.<sup>34</sup> As stated in a 1993 letter from PM Europe research and development employee, JB Boder, to Manuel Bourlas, PM senior manager:

"There are two international organizations controlled by the industry: CORESTA and ISO . . . CORESTA which is 100% controlled by the industry . . . ISO technical committee 126 is

made of approximately 80% Industry . . . The best way to work with these two organizations is to do all the technical work within CORESTA and then have it endorsed by ISO."<sup>24</sup>

CORESTA conducts its work on tobacco products standards through one of several mechanisms: suggesting new standards and work items,<sup>33-35-36</sup> revising current standards<sup>32</sup> or responding to ISO's request for research in the establishment of a new standard.<sup>37-38</sup> Draft standards prepared by CORESTA are eventually circulated to the technical committee's member bodies for approval and standards are approved as recommended by CORESTA, with limited opportunity for significant amendments. For example, the minutes of a CORESTA's environmental tobacco smoke (ETS) subgroup meeting in Paris in April 1997 state:

"The draft international standard ISO/DIS 11454 'Tobacco and tobacco products—determination of vapour-phase nicotine in air—gas chromatography method' was approved and will be published without change, other than editorial, as an international standard. (This standard is technically the same as CORESTA recommended method 14)."<sup>39</sup>

This arrangement is favourably perceived by the tobacco industry. As per a document describing the technical committee 126:

"It is unnecessary to describe CORESTA in detail. Suffice to say that the relationship with ISO/TC 126 is such that CORESTA does the science and the collaborative testing and produces recommended methods which are subsequently submitted for conversion into International Standards. If a work proposal is accepted by ISO/TC 126 and study is required, it is almost always referred to the appropriate study group in CORESTA. This procedure has worked extraordinarily well in the revision of ISO 3308, 3402, 4387, 8243 and the issue of 10315 and 10362."<sup>33</sup>

The chairperson of technical committee 126 is PI Adams, who used to work for Imperial Tobacco Ltd,<sup>40-41</sup> is credited with the invention of a type of ventilated filter,<sup>42</sup> served as president of CORESTA's technology group,<sup>43</sup> and is listed as an "industry consultant" to the Tobacco Manufacturers Association.<sup>44-45</sup>

In addition to methods for measuring tar and nicotine yield, CORESTA also provides ISO with research to establish standards in other areas such as: methods for determining organochlorine pesticides residues,<sup>46-47</sup> methods for preparation, conditioning, and sampling of fine cut tobaccos and smoking articles,<sup>46</sup> analysis of genetically modified tobacco,<sup>47-50</sup> and determination of nicotine in ETS through gas chromatographic methods.<sup>51-52</sup>

Moreover, CORESTA conducts research in preparation for future standard needs in the areas where there has not yet been enough agreement within the industry that standards are needed. Such areas include ETS components and non-smoker exposure to these components,<sup>51-53</sup> cigar, pipe, and cut tobacco smoking, and roll-your-own (RYO) cigarettes, among others.<sup>46-49-51-54</sup>

CORESTA works with ISO either directly or through one of ISO's member bodies, such as



the British Standard Institute (BSI) or American National Standards Institute (ANSI).<sup>32 44 55</sup> (At a CORESTA's ETS subgroup meeting in Paris in April 1997 it was stated that ultraviolet absorbance and fluorescence methods described in document ISO/TC 126 N 554, "Environmental tobacco smoke-estimation of the contribution to respirable suspended particles—ultraviolet absorbance and fluorescence methods" would be accepted by ISO as a new work item and that Mike Ogden, from RJ Reynolds (RJR) tobacco research and development department would be confirmed as project leader.<sup>39</sup>) For example, Helmut Reif's (from PM worldwide scientific affairs) monthly report for May 1998,<sup>56</sup> described the "regular meeting of the scientific commission of CORESTA" and stated:

"... a method for ETS determination (quantification by UVP and FPM) sent via ANSI (M Ogden) to ISO. It was seen necessary to make it clear in a preamble that this method would only be able to determine RSP that stem from any combustion process and therefore cannot be seen as specific for ETS."<sup>56</sup>

CORESTA expanded from a mere scientific entity to become more involved in political issues that concern the industry, such as regulatory policies,<sup>38 57</sup> but there was apprehension that by becoming too politically involved CORESTA's scientific credibility could suffer,<sup>58 59</sup> particularly in the area of pesticides. Nonetheless, the 1983 minutes of the scientific committee states, "thanks to the pesticide subgroup, the industry was in a better position for discussion with the regulatory authorities."<sup>60</sup> And in a 1989 report of a CORESTA board meeting in Rome, where a review of smoking procedures methods was discussed, PM's Manuel Bourlas stated that:

"The situation today however, is that 'regulatory authorities' DO play an important role in the analytical methods which are used and play an even larger role in 'printed numbers'." [emphasis on original]<sup>61</sup>

#### NON-CORESTA PARTICIPATION IN ISO TC 126

ISO's member bodies are entitled to participate and exercise full voting rights on any technical committee and policy committee of ISO. A member body takes the responsibility for "informing potentially interested parties in their country of relevant international standardisation opportunities and initiatives; and "ensuring that a concerted view of the country's interests is present during international negotiations leading to standards agreements."<sup>71</sup> Despite the stated openness for input from interested parties, CORESTA resists any interference with its proposed standards, and make efforts to keep overall control of the situation and the outcomes of ISO meetings. For example, the minutes of CORESTA's outgoing scientific commission meeting in Japan in 1996 stated:

"The subgroup routine analytical chemistry has prepared a series of editorial updates of the smoking methods. Shortly before the ISO meeting in Williamsburg in October 1996, the British body (BSI) sent a number of proposals on the same topic and at the meeting it was clear that some non-CORESTA participants, in particular

government labs, were eager to have their say, with the support of ISO itself.

"After the meeting of ISO, it is clear that if the CORESTA methods and ISO standards are to remain close or identical, it is not desirable to publish revised CORESTA methods immediately, but to hand out a draft and wait for eventual ISO amendments, then publish a revised version very close to the ISO revised standard."<sup>57</sup>

Further, while addressing the issue of standards for RYO, the same minutes stated: "At the ISO meeting, the matter of participation of non-CORESTA bodies to the experimental work was raised and has to be addressed."<sup>57</sup> The proposed solution to this "outsider" participation was that after methods have been determined by CORESTA, a subgroup will work on the validation of the methods, at which stage "outside bodies such as government labs could then be invited to participate..."<sup>57</sup> (The industry was concerned that problems with reaching an agreement over methods for measuring RYO tar and nicotine yield would lead to a cooperation with government laboratories.<sup>48</sup>)

#### CORESTA AND ISO RELATIONS WITH WHO AND OTHER ORGANISATIONS

ISO has official status as a non-governmental organisation with WHO, which provides the tobacco industry, through ISO/TC 126, access to WHO and the United Nations' Food and Agriculture Organization (FAO). (In addition, WHO has an observer status with ISO, and CORESTA has an official "liaison" with FAO.)

In 1990 one of CORESTA's consultants was a Dr Vitorazzi, an asset to the industry as he was "personally acquainted to most of the main players in the WHO/FAO business, due to his former assignment as secretary of the joint working group..."<sup>38</sup> and who due to his old contacts "can approach all files of WHO, even the classified ones..." while he was working on pesticide issues for CORESTA.<sup>38 58</sup> In 1993, while still working as a CORESTA consultant, Vitorazzi was an invited temporary advisor on the joint FAO/WHO meeting on pesticides residues.<sup>62</sup> (The tobacco industry interest in FAO is, at least partly, out of concern with pesticide use and pesticide residues allowance regulations. CORESTA's involvement with FAO on pesticides residue regulations intensified in 1974.<sup>63</sup> Pesticides residues allowances are a concern of the industry because they are usually based on leaf residues and not on health effects of the residues in the final product—cigarette. This often leads to lower levels allowed than desired by the industry.)

In addition to WHO and FAO, ISO/TC 126 also participates in other multisectoral collaboration of the United Nations agencies on issues of tobacco and health, providing information about the works of ISO/TC 126 to, for example, the United Nations Conference on Trade and Development (UNCTAD).<sup>27 34</sup>

Although CORESTA represents the industry, individual companies also develop their own strategies to protect their commercial interests in the face of standards and

regulations. An example is PM's "Europe science and technology defensive activities for 1983-1988" that list, among others, objectives and strategies to contact scientists and officials, including at WHO, to "learn about their intentions, to modify their opinions, to precede their interventions with national government agencies . . ." <sup>64</sup> to extend and deepen PM's position within CORESTA, and:

"Further deepening of contacts by PM experts with standardizing organisations and with institutions that carry out control measurements on cigarettes, ingredients, or other relevant commodities in order to assure that *PM products are measured* correctly throughout the world, and that they find universal acceptance.

"Strategies: Initiative by PM representatives in directing the activities of the International Standards Organization (ISO) and the various national standardizing committees in the *PM sense* as well as actively collaborating in joint experimentations with national testing organisations (e.g. LGC, Canton Chemists, BGA) so as to assure that *PM methodology, PM instrumentation, PM laboratory practices* find the widest possible acceptance, and that *PM products are tested in a fair way*." <sup>64</sup> [emphasis in original]

In 1990, PM continued to attempt to grow its influence in the works of ISO and CORESTA and wanted these organisations to:

" . . . provide better support for the Industry (and PM) by taking a more aggressive position in the technical/scientific tobacco environment. Without implying that they should jump into the smoking and health controversy, I think there are many issues which they could handle with good chances of success. For example:

- Tolerated pesticide residues levels
- Approved tobacco additives
- ETS studies
- Approved packaging materials
- etc . . ." <sup>24</sup>

#### PHILIP MORRIS VERSUS BRITISH AMERICAN TOBACCO: THE LOW TAR DEBATE

One of the areas where ISO standards have best served the industry is through providing the impression of legitimacy to industry claims that cigarettes with lower levels of tar and nicotine yield were less harmful. <sup>6 16</sup> A discussion over one particular low tar claim led to one of the largest "insider" battles of the tobacco industry.

Although in the area of standards, the tobacco companies tend to agree, this agreement is not always easily reached. Commercial interests and proprietary issues often create conflict in the work of CORESTA and ISO. One of such disagreements occurred in the early 1980s, over whether or not British American Tobacco (BAT) channel ventilated cigarettes should be submitted to the same analytical tests as non-channel, conventionally ventilated cigarettes. (Channel ventilation was a design that brought additional airflow into the cigarette filter.) Conventionally ventilated filters dilute mainstream smoke through a variety of mechanisms, used alone or in combination, mainly: creation of holes in the filter itself, increased air permeability, and porosity of the paper used to wrap the filter and the tip of the cigarette, all part of the filter itself and with the intent of creating holes in the filter. <sup>65 66</sup> Holes in

cigarette filters were invented to "cheat" smoking machines that measure tar and nicotine yield, by allowing air to flow into the machine and diluting the concentration of cigarette smoke components. It has been demonstrated that human smokers compensate for lower delivery by, among other things, blocking those holes. <sup>2 3 6 15</sup> Channel ventilated cigarettes were able to yield even lower tar reading through the standard smoking machine method (ISO/DIS 4387) by bringing additional fresh air in the smoke through its channels. These cigarettes used the:

" . . . so-called 'Actron' filter which provides ventilation through four peripheral channels which are isolated from the core of the filter. When a human being smokes this cigarette, his lips inevitably block some of the peripheral channels, so that the cigarette delivers significantly greater amounts of tar when smoked by human beings than when tested on a smoking machine." <sup>67</sup>

BAT marketed the new product, Barclay, as an "ultra-light" cigarette with only 1 mg of tar. (The reported 1 mg of tar was actually 5 mg when the channels in the filter were blocked. <sup>68</sup>)

PM protested that BAT could not market its products based on a reading by a method not appropriate for channel ventilated filters. It considered channel ventilation a "leakage" (false air entering the cigarette holder) rather than "ventilation" (dilution). <sup>7</sup> BAT's argument was that:

" . . . all ventilated cigarettes produce higher deliveries during human smoking than during machine smoking, and that even though this difference is greater in channel-ventilated cigarettes it is not reason enough to treat these cigarettes differently." <sup>69</sup> [emphasis on original]

The industry documents addressing the BAT/PM disagreement provide insight on how aware the cigarette companies were that by creating a special type of filter they were able to reduce the readings of tar and nicotine without compromising the taste of the cigarette. ISO meetings became the arena for the BAT and PM battle. The debate over adequacy the testing methods for the channel ventilated cigarettes started at an ISO meeting in Paris in September 1985, <sup>70</sup> continued in 1986 in Turkey, <sup>69 71</sup> and 1988 in China. <sup>72 73</sup> By 1989, an agreement was reached between the two companies. It was agreed that CORESTA would work on developing a new testing method that would address issues related to measuring yield in channel ventilated cigarettes (without changing measurements of "conventional" cigarettes), and that both companies would work toward "a smooth and rapid adoption of the new method". <sup>74</sup> It was also agreed that PM would stop litigation in regards to Barclay. It was not a change in the yields of either conventional or channel ventilated cigarettes, but a rather an agreement on how the data would be reported. <sup>74-76</sup>

Measurement methods continued to be a commercial and operational concern for the industry. Indeed, a 1990 PM memo discussing the fact that a few countries have their own measuring standards stated:

"Tar delivery of cigarettes depends upon the smoking method used, and no one method can be said to be more correct than another.

"As a result of this lack of agreement on a standard smoking method, governmental regulators within each country have arbitrarily defined standard smoking method for their country to provide consumers with a relative ranking of tar delivery of cigarettes and to regulate the advertising of cigarettes. As an example of the magnitude of these different methods, the tar delivery of a full flavoured Marlboro will vary by as much as 2 mg, depending upon the smoking method used. This becomes critical in those countries where we are required to print tar delivery on the packs and the tar delivery is verified by "official" governmental laboratory . . .

"If we accept the 2 mg lower limit as in this Standard [ISO/DIS 4387], we run the risk of losing the ability to advertise a product as 1 mg in those countries that do not have a "regulatory authority" to confirm the data . . .

"If we are successful in developing new ISO methods that are adopted by the EEC countries, it should also be adopted by the other countries that follow ISO standards. I would recommend that PM work towards having the ISO smoking methods adopted by those countries that do not traditionally follow ISO standards. This includes US, Japan, Gulf Coast Countries, the Pacific Rim Countries, South America and anywhere else we either sell or plan to sell cigarettes."<sup>68</sup>

#### INTERNATIONAL VENTILATION STANDARDS—ISO/TC 205

In addition to consumer products, standards are also utilised to determine air and water quality. For example, the indoor air quality in office buildings is determined according to a set of standards which in turn are used to guide health and safety policies and regulations. In the USA, the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) is the organisation appointed by the American National Standards Institute (ANSI) to address indoor air quality standards. In turn, ISO relies on ANSI/ASHRAE standards to develop international air quality standards.

A less discussed fact is the tobacco industry involvement with ISO's technical committee 205—building environment design, mainly with its working group 4: indoor air quality. Given the priority the industry has given in the past few years to the issue of regulation of indoor smoking, this committee is likely to assume a greater importance in the industry's view. The tobacco industry documents provide ample evidence of the industry's interest and influence on ISO/TC 205 and on ventilation and indoor air quality standards.<sup>39 48 77–80</sup> An in-depth discussion of these documents is beyond the scope of this paper. However, it is noteworthy that in the future, the industry is likely to exert greater pressure on ISO/TC 205. Until the year 2000, the international standard for indoor air quality has been essentially the same as ASHRAE standard 62-1989. (ASHRAE has revised standard 62-1989, which is now standard 62-1999, with addenda 62 c-f approved and others still under review. It provides stricter ventilation standards for separating ETS areas from ETS-free areas. It will

be interesting to see if ISO will adopt the revised standard.)<sup>81</sup>

#### Discussion

The tobacco industry dominates the process of tobacco and tobacco products standard setting to advance its political and commercial needs, therefore pre-empting the passage of regulatory policies that would indeed protect the health of the public. In the area of cigarettes and other tobacco products, the establishment of international standards has failed to protect consumers' health and safety, due largely to the influence of the tobacco industry. One of the areas where the overarching influence of the tobacco industry is most blatant is in the determination of tar and nicotine yield in cigarette smoke. For several decades the tobacco industry has been *de facto* responsible for determining the ISO standards on tobacco and tobacco products. Tar and nicotine measurement based on those standards have been widely used by the industry to promote its products as "mild", "lights" and "ultra-lights", for example, insinuating health benefits from these lower tar and nicotine products, when no health benefits exist.<sup>6 9 15 16</sup> (In 1962, in Canada, the tobacco industry agreed to avoid using tar and nicotine levels in advertising, a deal that fell apart in the mid-seventies, with an increase in the competition for the "light" cigarettes market.<sup>82 83</sup>)

It is clear that ISO standards serve only to rank cigarettes according to the tar and nicotine yield when smoked by a machine and that is not reflective of human smoking. ISO standards on tobacco and tobacco products should not be used to measure the health impact these cigarette smoke components have on the smoker as well as on the environment. There is an urgent and long overdue need for public health professionals to push for meaningful changes in the way tobacco related standards are developed, and how they are used. For example, Koslowski and O'Connor suggested a "two stage" compensating test that would provide a more accurate reading of tar and nicotine yield and of tar/nicotine ratios than the existing methods by not only testing cigarettes under more intense smoking conditions (higher volume puff, shorter interval) but also through blocking filter ventilation.<sup>9</sup>

Health advocates in Canada have already convinced the government that current standards on tobacco are deceptive. Both the British Columbia and federal governments modified the ISO methods to produce more realistic readings of the levels of tar and nicotine and other components yields. The Canadian modification provides a range of yields under regular and intense smoking conditions. It is still just a rank of tar and nicotine level as per machine smoke and not a measure of health effects—it may not be possible to estimate precisely a human exposure, as each smoker will smoke in slightly different ways—but it allows for more accurate information to be provided to consumers.<sup>10</sup> This is relevant as legislation regarding package labelling



displaying levels of tar and nicotine is being considered, both in Canada and elsewhere, and in face of the proposed European directive.<sup>17</sup> The 1999 European directive determines, among other things, that tar levels should not exceed 10 mg and nicotine levels should not exceed 1 mg, by the year 2003, according to ISO measurement methods. This is an update from a 1990 European directive limiting the amount of tar to 15 mg. To comply with the early directive, the industry changed measuring methods without changing the product, as stated in this 1993 memo from PM's M. Bourlas:

"You already know about the EEC mandate to reduce all deliveries to 15 mg. As we knew this was going to happen as early as 1988, we began to develop a strategy with which to react. The strategy centred around the fact that there existed a number of different testing procedures around the world and it seemed prudent on our part to harmonize them. Spearheaded [sic] by PM Europe, we put together a team represented by 23 different markets (countries) and began the task of standardization. The 3 year effort resulted in a new method (now known as 'new ISO') which reduces the smoke delivery results by about 1 mg at the 16 mg level. The Marlboro sold in the EEC was initially delivering about 15.5 mg, prior to any analytical methodology change. When the new system was implemented, the deliveries were around 14.5 mg, but remember, no product change ever took place . . ."<sup>18</sup>

It is likely that the tobacco industry has already develop strategies to deal with the new European Directive in a manner that will be most beneficial to its interests, such as changing cigarette design. Thus, continuing to make health policy decisions based on current ISO standards is meaningless and is a step back in the tobacco control and consumers' protection movements.

The final report from the WHO's sponsored meeting "Advancing Knowledge on Regulating Tobacco Products" held in Oslo, Norway in February 2000<sup>20, 21</sup> acknowledges that:

"FTC/ISO methods currently in use were not intended to measure the biological or epidemiological impact of tobacco products. New methods and protocols must be developed to measure the impact of tobacco products on an individual and population basis. ISO should be urged to ensure that its members recognize and adhere to the principle that ISO/FTC measurement and methods are used to monitor performance and not health impacts of tobacco products."<sup>20</sup>

The report recommends:

"Ban the use of misleading terms such as "light", "mild", and other words or imagery (including certain brand names) which have the aim or effect of implying a reduced health risk attributable to low tar or nicotine measurements on tobacco products and in advertising/promotional material.

"Remove tar and nicotine measures derived from ISO/FTC methods from packages. Warning labels to emphasize the addictiveness of tobacco products.

"Discontinue harm reduction strategies based on naïve interpretation of tar and nicotine yield measurements. This means abandoning the strategy of seeking lower nominal tar yields and

instead, finding approaches that genuinely reduce harm to nicotine users."<sup>20</sup>

The issue of standard measurement of tobacco products components is likely to gain even more international visibility as the negotiations for the Framework Convention for Tobacco Control advance and include the regulation of tobacco products among its protocols.

Each government could follow Canada's example, but it would be more effective if health professionals and tobacco control groups attempt to participate in the work of ISO, either directly or through a national standard organisation. It is unlikely that every single ISO member will be able to set its own measurement standards, as the tobacco industry knows which is why it prefers to work through international organisations. As stated in a 1990 PM document:

"The main disadvantage of arguing with local authorities is that it is very difficult to find technically competent people and/or that we often have to face the anti-smoking lobby and the debate then becomes emotional. On the other hand, if a 'precooked' solution is proposed by a credible international organisation it is often accepted 'as is' because of the fear of going against international trends."<sup>24</sup>

The need for groups other than the tobacco industry to become involved with the work of ISO is even more pressing because, in an attempt to streamline and speed its procedures ISO is considering some procedural changes that will give the tobacco industry greater opportunity to determine international standards:

"ISO committees will in future, subject to certain conditions, have the option of dispensing with the committee stage—the part of the ISO process during which national positions are debated in order to reach consensus within an ISO committee—and with the final approval stage, during which the texts of final standards are submitted for formal approval by the full ISO membership . . .

"New deliverables representing the consensus between technical experts in an ISO working group or an international consensus achieved in an ISO committee allow publication of new types of documents, called, respectively, Publicly Available Specification (ISO/PAS), and Technical Specification (ISO/TS). ISO will also provide the possibility for adoption of documents developed outside the ISO system by less transparent and consensual procedures. Such documents, whether developed within or outside the ISO system as ISO/PAS or ISO/TS, must be reviewed every three years and at the second review must either be withdrawn or revised to become full ISO International Standards."<sup>21</sup>

The time for health groups to act is now. With the knowledge accumulated it is no longer acceptable that claims of lower levels of tar and nicotine be made based on ISO standards measurement methods.

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### What this paper adds

It is widely known by public health professionals that the ISO standard methods to measure tar and nicotine content in cigarettes are inadequate to assess the amount of human exposure to these components, underestimating the actual yields. The tobacco industry has taken advantage of the ranking provided by these standards to mislead the public, using labels such as "mild" and "light" for cigarettes that have lower tar and nicotine contents according to the ISO method, implying a non-existent health benefit.

This analysis of internal tobacco industry documents shows how the industry is *de facto* responsible for setting these standard measurement methods, from the testing development to the approval and publication stages. Based on evidence of industry influence provided by this analysis, this study urges public health authorities to play a larger role in the standard setting arena, and to refuse to use the ISO method as a basis to develop health related regulatory policies. The ISO standard, as is, should not be used to justify policies aiming at protecting the public's health.

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